

## REMARKS

Original independent claim 1 has been amended, and new independent claims 5, 11 and 18 have been added, along with new claims 6 - 10 dependent on claim 5, new claims 12 - 17 dependent on claim 11, and new claims 19 - 22 dependent on claim 18.

The prior art cited by the Examiner shows lancets having a cap joined to a lancet body by a frangible connection. In Marshall et al., the cap has a rib that is pressed onto the exposed needle with the rib fitting into a recess on the distal end of the lancet body. In Morita, the cap has a cylindrical opening to matingly engage the distal end of the lancet body when pressed onto the exposed needle, the opening facing in the radial direction relative to the main axis of the lancet body prior to removal, i.e., the opening faces to the side.

Claim 1 has been amended by adding the language of original claim 4 (now canceled) such that the claim now requires “an interior axially projecting hub for receiving at least a portion of said piercing tip embedded therein when said cap is placed on said lancet distal end”. The prior art does not anticipate under Section 102 nor make obvious under Section 103 this feature. The Examiner states that element 42 of Morita is an interior axially projecting hub, but it is respectfully submitted that this is an improper interpretation of the Morita device. Element 42 of Morita is defined therein to be an “elongate recess” and its function and operation is set forth in col. 6, lines 16 - 31. As expressly stated by Morita and as shown in Figures 11 and 12, element 42 is the exact opposite of the required “projecting hub” of claim 1 as amended. The projecting hub, element 46 of the application at hand, projects, i.e., it increases the thickness of the cap on its central axis where the needle is received. The elongate recess 42 of Morita decreases the thickness of the cap on its central axis where the needle is received. In short, a recess cannot be a projection.

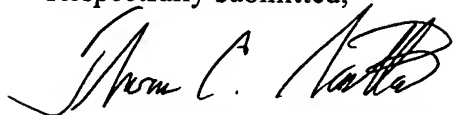
New claim 5 requires a lancet wherein the opening of the cap that mates with the lancet body distal end is “facing in the distal direction away from said lancet body prior to separation of said frangible junction and removal of said cap from said lancet body”. In the prior art shown by the Morita patent, the opening faces to the side, i.e., in the radial direction, when the cap is still attached to the lancet body. To place the cap on a surface for insertion of the needle into the cap after use, the user must determine the orientation of the Morita cap as held and then properly translate or rotate the cap to set its contact base onto the support surface. With the invention, the cap is properly oriented in the user’s fingers upon removal, so no rotation or translation is needed to set it onto the support surface.

New claim 11 requires a lancet wherein the opening of the cap that mates with the lancet body distal end is “coaxially aligned with said shaft prior to separation of said frangible junction and removal of said cap from said lancet body”. As argued above, this is patentably distinct in that the opening of Morita is not coaxially aligned prior to separation.

New claim 18 requires a lancet wherein the cap itself is “generally cylindrical and coaxially aligned with said shaft prior to separation of said frangible junction and removal of said cap from said lancet body” and having “at least one tab member projecting radially from said cap member”. This combination of cylindrical cap coaxially aligned and having a radially projecting tab member is not anticipated nor made obvious by the prior art. In the prior art lancets, the axis of the cylindrical cap is perpendicularly oriented relative to the axis of the needle shaft.

It is respectfully submitted that the claims as now presented are patentable, on the basis of the above remarks, and reconsideration and subsequent passage for allowance is hereby requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Thomas C. Saitta". The signature is fluid and cursive, with a large, stylized initial "T" and "S".

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